510(k):
K094030

CASMED®

DEC 23 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	CAS Medical Systems, Inc.
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Prepared:	December 23, 2010
Trade Name:	FORE-SIGHT® Absolute Tissue Oximeter
Common Name:	Tissue Oximeter
Classification Name:	Oximeter, Tissue Saturation
Classification #:	21 CFR (870.2700)
Product Code:	MUD
510k:	K094030

DESCRIPTION

The FORE-SIGHT Oximeter, MC-2000 Series, measures brain and skeletal muscle tissue oxygen saturation.

The FORE-SIGHT Oximeter consists of an optical transducer containing a laser light source and photodiode detectors, and a graphic display with user interface. The noninvasive, reflection mode, optical transducer is placed on the forehead (brain) or skeletal muscle, via a disposable sensor to determine tissue oxygenation. The FORE-SIGHT Oximeter is safe to use because it is designed to operate as a class 1 laser product, the safest FDA laser classification. Additional safety features include a laser interlock system, designed to prevent laser operation in case the optical transducer is not securely attached to the subject.

FORE-SIGHT Oximeter Indications for Use

The FORE-SIGHT® Oximeter, Model MC-2000 Series is indicated for the continuous noninvasive monitoring of regional hemoglobin oxygen saturation of blood in the brain and skeletal muscle. It is intended for use in any individual at risk for reduced-flow or no-flow ischemic states.

When used with Large sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of adults and children over 40 kg. When used with Medium sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of small adults and children between 4 and 80 kg. When used with Small sensors, the FORE-SIGHT Oximeter is indicated for use on the brain of infants and neonates $\leq$ 8 kg.

When used with Medium sensors, the FORE-SIGHT Oximeter is indicated for use on skeletal muscle of infants, children and adolescents between 5 and 50 kg.

The prospective clinical value of data from the FORE-SIGHT Oximeter has not been demonstrated in disease states and these data should not be used as a sole basis for diagnosis or therapy.

FORE-SIGHT Oximeter Technology Compared to Predicate Devices

The FORE-SIGHT Oximeter compares substantially to one or more of the cited predicate devices in that they use fundamentally the same optical operating principle, called diffuse reflectance spectroscopy. All cited monitors use light to probe a cross-section of tissue microvasculature (i.e., a mixed bed of arterioles, capillaries and venules). The FORE-SIGHT Oximeter and predicate devices analyze light returning from the sampled tissue, after having passed through tissues, for hemoglobin in its oxygenated and deoxygenated forms. All cited monitors calculate oxygen saturation. This value reflects the percentage of oxygenated hemoglobin in the sampled tissue.

EQUIVALENCE (Predicate Device)

The FORE-SIGHT® Oximeter, MC-2000 Series, is equivalent to the following devices:

- ❖ CAS Medical Systems Cerebral Oximeter (K091452)
- ❖ Somanetics Corporation INVOS® 5100C Cerebral/Somatic Oximeter (K082327)
- ❖ Hutchinson Technology InSpectra™ StO_2 Tissue Oxygenation Monitor, Model 650 (K100915)
- ❖ Spectros Corporation T-Stat™ 303 Microvascular Tissue Oximeter (K081233)

Comparison Table

Predicate Device	**Similarities to FORE-SIGHT K 094030**	**Differences from FORE-SIGHT K 094030**
CAS Medical Systems FORE-SIGHT Oximeter (K091452)	• Same laser light source/energy; • Same four wavelengths; • Same sensor / monitor design; • Same physiological purpose; • Cerebral tissue oxygen saturation measurement; • Same "cerebral" IFU; • Same small, medium and large sensor sizes for cerebral; • Same cerebral performance.	• Slight modifications of algorithm; • Slight user interface changes; • Added skeletal muscle monitoring with medium sensors for specific patient groups/weights
Somanetics Corporation INVOS 5100C Oximeter (K082327)	• Tissue oximeter; • Cerebral and somatic monitoring; • Same hospital area of use; • Same patient population groups for cerebral monitoring; • Same parameter measured; • Adhesive sensor.	• IFU includes cerebral for all individuals sensor size dependant; • Infants, children and adolescent population for skeletal muscles; • LED light source, two wavelengths, LEDs in sensor; • Trend monitor <2.5 kg.
Hutchinson Technology InSpectra StO_2 Tissue Oxygenation Monitor (K100915)	• Tissue oximeter; • Four wavelengths; • Fiber optics used; • IFU includes skeletal muscle; • Adhesive sensor.	• LED light source; • Specific patient population not identified.
Spectros Corporation T-Stat Microvascular Tissue Oximeter (K081233)	• Tissue oximeter, • Broad bandwidth white light; • Fiber optics used; • IFU states microvascular tissue spaces; • Various needle or probe- like sensors.	• Visible white light source; • Specific monitoring sites not identified.

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The FORE-SIGHT Oximeter, MC-2000 Series has been tested to the following standards in accordance with CAS Medical Systems Product Performance Specifications:

- UL 60601-1 Safety testing for use of the UL Classified mark;
- CAN/CSA C22.2 No. 601.1-M90;
- IEC 60601-1 Safety of Medical Electrical Equipment;
- EN 60601-1 Safety of Medical Electrical Equipment;
- IEC 60601-1-1 Safety of Medical Electrical Systems;
- IEC 60601-1-2: 2001 Safety of Medical Electrical Equipment with regard to EMC Emissions and EMC Immunity;
- IEC 60601-1-4 Safety of Programmable Electrical Medical Systems;
- IEC 60601-1-8 Safety of Alarm Systems for Medical Equipment/Systems;
- IEC 60825-1: Safety of Laser Products (with amendments A1 and A2)

In addition to the above laboratory tests, CAS has conducted a full program of individual hardware, software and systems monitor and sensor verification and validation studies.

Clinical Testing to Demonstrate Substantial Equivalence

Pediatric Subject Skeletal Muscle Validation: CO-oximetry data from invasive arterial and venous blood samples from sites representative of skeletal muscle were respectively compared to FORE-SIGHT Oximeter values. FORE-SIGHT sensors were placed over skeletal muscle of adolescents, children, and infants undergoing examination in a catheterization laboratory.

Conclusions Drawn from Clinical and Non-Clinical Testing

When compared to CO-oximetry measurements, the precision (1 Standard deviation) of FORE-SIGHT Oximeter values (StO_2) were ± 4.9 % for skeletal muscle in human subjects. The precision of FORE-SIGHT Oximeter values were comparable or better than the predicate devices, when compared to CO-oximetry measurements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

CAS Medical Systems, Inc.
% Mr. Ron Jeffrey
Director, Regulatory Affairs
44 East Industrial Road
Branford, CT 06405

DEC 2 3 2010

Re: K094030
Trade/Device Name: Fore-Sight Absolute Cerebral and Somatic Oximeter, MC-2000 Series
Regulation Number: CFR 21 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: November 8, 2010
Received: November 9, 2010

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 2 3 2010

510(k) Number: K 094030

Device Name: FORE-SIGHT® Absolute Tissue Oximeter
Model MC-2000 Series.

Indications for Use:

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Prescription Use _✔__ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K094030